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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/662,777 | 09/15/2003 | Hassan Ahmad | 2551-1-001 | 1508 |
| 23565 | 7590 | 09/13/2006 | | |
| KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601 | | | | |
| EXAMINER | | | | |
| MCCORMICK EWOLDT, SUSAN BETH | | | | |
| ART UNIT | | PAPER NUMBER | | |

1661

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TH

Office Action Summary

Application No.

10/662,777

Applicant(s)

AHMAD ET AL.

Examiner

S. B. McCormick-Ewoldt

Art Unit

1661

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-25 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) 11-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment of July 3, 2006 is hereby acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant elected Group I and *Nigella sativa*, in the reply filed February 24, 2005.

Claims 11-25 are withdrawn from further consideration.

Claims Pending

Claims 1-2, 4-25 and 27-29 are pending. Applicant has cancelled claims 3 and 26.

Applicant has added claim 29. Claims 1-2, 4-10 and 27-29 are examined.

Claim Objections

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 6, [0014]). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1661

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 5, 8 and 27-29 are rejected under 35 U.S.C. 102(a) as being anticipated by Khan *et al.* ("The *In Vivo* Antifungal Activity of the Aqueous Extract from *Nigella sativa* Seeds," *Phytotherapy Research*, Vol. 17, No. 2, pages 183-186 (February 2003)).

Khan *et al.* teach a therapeutic (pharmaceutical) composition comprising a buffered aqueous (i.e. phosphate buffered saline) extract of *Nigella sativa* seeds within the claimed concentration range (i.e., above 20% weight per volume)- see e.g. page 183, column 2, paragraph 2. Please note that the PBS reads upon a pharmaceutically acceptable carrier.

Accordingly the reference is deemed to anticipate the instant claims above.

Applicant is requested to note that it is regarded that "intended use" of a composition or product (e.g. treating hepatic disorders and/or increasing the number of immune cells) will not further limit claims drawn to a composition or product. See, e.g., *Ex Parte Masham*, 2 USPQ2d 1647 (1987) and *In Re Hack* 114, USPQ 161. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1661

Claims 1, 4-8, and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khan *et al.* ("The *In Vivo* Antifungal Activity of the Aqueous Extract from *Nigella sativa* Seeds," *Phytotherapy Research*, Vol. 17, pages 183-186 (February 2003)).

Khan *et al.* beneficially teach a therapeutic composition comprising a buffered aqueous (i.e. phosphate buffered saline) extract of *Nigella sativa* seeds within the claimed concentration range (i.e., above 20% weight per volume) for effective use as an anti-fungal agent (see entire document including, e.g. page 183, column 2, paragraph 2).

It would have been obvious to one of ordinary skill in the art the time the claimed invention was made to prepare a therapeutic pharmaceutical composition comprising a buffered aqueous extract of *Nigella sativa* (PBS extract) based upon the beneficial teachings provided by Khan *et al.* with respect to the effective anti-fungal activity thereof. The adjustment in conventional working conditions (e.g., incorporating the anti-fungal extract taught by Khan *et al.* within a commonly employed delivery vehicle routinely used for such anti-fungal agents- such as within a table/capsule, suspension, spray, transdermal, suppository; and/or sterilizing such therapeutic composition for standard safety/self-life considerations) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference.

Summary

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1661

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiners' supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme


CHRISTOPHER R. TATE
PRIMARY EXAMINER